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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,103	05/30/2006	Peter Petzelbauer	1848-7 PCT/US	2050

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HOFFMANN & BARON, LLP
6900 JERICHO TURNPIKE
SYOSSET, NY 11791

EXAMINER	
HA, JULIE	

ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,103	PETZELBAUER ET AL.	
	Examiner	Art Unit	
	JULIE HA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to comply to sequence rule*.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 23, 2009 has been entered. Claims 17-28 are pending in this application.

Sequence Non-compliance

Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below. **All sequences disclosed in the application must comply with the requirements of 37 C.F.R. 1.821-1.825, not only those recited in the claims.**

The sequence recited in claim 17 does not correspond to any sequences in the sequence listing. Claim 17 recites, a sequence DKKREEAPSLRPA**PPPI**SGGGYR. However, none of the sequences listed in the sequence listing discloses the above sequence. SEQ ID NO: 3 discloses the sequence

GHRPLDKKREEAPSLRPAPPPISGGGYR. SEQ ID 1 discloses the sequence DKKREEAPSLRPA**PPI**SGGGYR. However, this sequence has 2 prolines and the sequence recited in claim 17 has 3 prolines (as indicated by bold fonts).

All such sequences are relevant for the purposes of building a comprehensive database and properly assessing prior art. It is therefore essential that all sequences, whether only disclosed or also claimed, be included in the database.

Applicant is given **ONE MONTH**, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply. **Please note that examination cannot continue unless the sequence compliance rule requirements are fulfilled.** The applicant should carefully review the specification for any other sequences, in order to avoid necessitating a second Notice To Comply and hindering prosecution.

Withdrawn Objections and Rejections

2. Claims 17-20, 23-26 rejected under 35 U.S.C. 112, second paragraph, as being indefinite, is hereby withdrawn in view of Applicant's arguments.

3. Claims 17-18 and 23-24 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with enablement requirement is hereby withdrawn in view of applicant's amendment to the claims.

4. Rejection of claims 17-18 and 23-24 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with written description requirement is hereby withdrawn in view of applicant's amendment to the claims.

5. Rejection of claims 17-28 under 35 U.S.C. 102(a) as being anticipated by Petzelbauer P (US 2004/0192596 A1) is hereby withdrawn in view of Applicant's arguments.

6. Rejection of claims 17-28 under 35 U.S.C. 102(a) as being anticipated by Petzelbauer P (US 2007/0037749 A1) is hereby withdrawn in view of Applicant's arguments.

7. Objection to claims 19-22 as not reciting sequence identifiers is hereby withdrawn in view of Applicant's amendment to the claims.

9. Objection to claims 19-20 as having spelling errors is hereby withdrawn in view of Applicant's amendment to the claims.

10. Objection to claims 23-28 as having minor informalities is hereby withdrawn in view of Applicant's amendment to the claims.

11. Objection to claims 23-28 as having spelling errors is hereby withdrawn in view of Applicant's amendment to the claims.

12. Rejection of claims 17-26 under 35 U.S.C. 112, second paragraph, as being indefinite is hereby withdrawn in view of Applicant's arguments.

Maintained Rejection

35 U.S.C. 112, second paragraph

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 23-28 recite the broad recitation "…wherein the shock is associated with one or more from…", and the claims also recite "…in particular through…" which is the narrower statement of the range/limitation.

Response to Applicant's Arguments

15. Applicant did not remark on this rejection.

16. Claims 23-28 recite broad limitation with narrow limitation within the same claim. Therefore, the claims do not clearly set forth the metes and bounds of the patent protection desired. Therefore, claims 23-28 are indefinite.

35 U.S.C. 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

18. Claims 17-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Petzelbauer P (US 2004/0192596 A1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Petzelbauer teaches the same formulae I and II as the instant formula II, see paragraphs [0002] and [0006]. Furthermore, GHRPLDKKREEAPSLRPAPPPISGGGYR (see SEQ ID NO: 294) that is the same as the one claimed in instant claims 17-22 and

the instant SEQ ID NOS: 2 and 3, meeting the limitation of claims 17-22. Furthermore, the instant claims 23-28 recite "...wherein the shock is associated with one or more groups comprising bacterial toxins, haemorrhagic shock following viral infection...infectious agents or autoimmune diseases, organ failure...and so on (see claims 23-28). Petzelbauer reference teaches the method of preventing inflammation in a subject comprising administering to the subject an effective amount of a peptide having the general formula II, wherein the inflammation is due to a condition selected from the group consisting of an infection, an autoimmune condition, a rheumatic disorder, or a disorder of the immune system (see claims 14 and 21). Since the cause that leads to inflammation and shock is the same, the method of treating inflammation would necessarily treat shock, and vice versa.

Response to Applicant's Arguments

19. Applicant argues that "USSN 10/459,030 (US 2004/0192596) is published on September 30, 2004. US 2004/0192596 is a continuation of International Patent Application No. PCT/AT01/00387, filed Dec. 7, 2001, published in German on Jun 20, 2002. As International Patent Application PCT/At01/00387 upon which USSN 10/459,030 is based was not published in English, publication US 2004/092596 is effective as a 35 U.S.C. 102(a) prior art reference only as of its publication date. Thus, this 35 U.S.C. 102(e) rejection is improper."

20. Applicant's arguments have been fully considered have not been found persuasive. US 2004/0192596 is a continuation of a PCT application, and has an effective filing date of June 11, 2003, which is a 35 U.S.C. 102(e) date. US

2004/0192596 (10/459,030) is not an US application publication of an international application after national stage entry. According to the MPEP 706.02(f)(1), for patent and US application publication: 102(e) date is the filing date of the US application that claimed benefit to the IA (see MPEP 706.02(f)(1)). Since the 102(e) date is the filing date of the US application, the filing date of US application is June 11, 2003, which is the 102(e) date. Therefore, the rejection is proper. The reference meets the limitation of instant claims 17-28.

21. Claims 17-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Petzelbauer P (US 2007/0037749 A1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

22. Petzelbauer teaches the same formula II as the instant formula II, see paragraphs [0007] and [0011]. Furthermore, the reference teaches the sequences GHRPLDKKREEAPSLRPAPPPISGGGYR (see SEQ ID NO: 294) that is the same as the one claimed in instant claims 17-22 and the instant SEQ ID NOS: 2 and 3, meeting the limitation of claims 17-22. The reference teaches that the invention consist of the preparation of pharmaceutical compositions for the therapy or prevention of local and/or

generalized inflammations in the body in case of infectious genesis, based upon autoimmune reaction, based upon a rheumatic disease, based upon a disorder in the immune system…for the prevention and/or therapy of the rejection occurring after organ transplants…" (see paragraph [0034]). The instant claims 23-28 recite "…wherein the shock is associated with one or more groups comprising bacterial toxins, haemorrhagic shock following viral infection…infectious agents or autoimmune diseases, organ failure…and so on (see claims 23-28). Claim 3 of the reference claims that the inflammation is due to a condition selected from the group consisting of an infection, an autoimmune condition, a rheumatic disorder, or a disorder of the immune system (see claim 3). Since the cause that leads to inflammation and shock is the same, and the reference claims a method of treating inflammation in a subject (see claims 1-4), a method of inhibiting inflammation of a transplanted tissue in a subject (see claims 5-6), the method of treating inflammation and inhibiting inflammation in a transplanted tissue would necessarily treat shock, and vice versa.

Response to Applicant's Arguments

23. Applicant argues that "USSN 11/542,050 (granted as US Patent No. 7,494,973 on February 24, 2009) published as US 2007/037749 on February 15, 2007 recites that the present application is a divisional of US Patent Application Ser No. 10/459,030 filed on June 11, 2003, which is a continuation of International Patent Application No. PCT/AT01/00387, filed Dec. 7, 2001, published in German on Jun. 20, 2002." Applicant argues that "As International patent application PCT/AT01/00387 upon which USSN

11/542,050 is based was not published in English, publication US 2007/0037749 is effective as of its publication date. Thus, this 35 U.S.C. 102(e) rejection is improper."

24. Applicant's arguments have been fully considered but have not been found persuasive. US 2007/037749 is a continuation of US application 10/459,030 filed on June 11, 2003. This is the priority date. US 2004/0192596 (10/459,030) is a continuation of a PCT application, and has an effective filing date of June 11, 2003, which is a 35 U.S.C. 102(e) date. US 2004/0192596 (10/459,030) is not an US application publication of an international application after national stage entry. According to the MPEP 706.02(f)(1), for patent and US application publication: 102(e) date is the filing date of the US application that claimed benefit to the IA (see MPEP 706.02(f)(1)). Since the 102(e) date is the filing date of the US application, the filing date of US application is June 11, 2003, which is the 102(e) date. Therefore, the rejection is proper. The reference meets the limitation of instant claims 17-28.

Obviousness Double Patenting

25. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

26. Claims 17-28 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 7,271,144. Although the conflicting claims are not identical, they are not patentably distinct from each other because if one practiced the claimed invention of instant application, one would achieve the claimed invention of U.S. Patent No. '144 and vice versa.

27. Instant claims are drawn to a method for treating shock comprising administering to a subject in need of such treatment an effective amount of a peptide of Formula II.

28. Claims 1-4 of U.S. Patent No. '144 are drawn to a method of treating inflammation in a subject comprising administering to the subject a peptide of SEQ ID NO: 294, wherein the inflammation is due to a condition selected from the group consisting of an infection, an autoimmune condition, a rheumatic disorder, or a disorder of the immune system.

29. U.S. Patent No. '144 claims the peptide of formula II of the instant claims, and teaches a method of treating inflammation in a subject comprising administering to the subject a peptide SEQ ID NO: 294, which is the same as the instant claims 17-22, and also teaches that the inflammation is due to the same conditions (infection, autoimmune disease, a rheumatoid disorder, or a disorder of the immune system) (see claim 3).

Therefore, if one practiced the claimed invention of the instant claims, one would necessarily achieve the claimed invention of the U.S. Patent No. '144 and vice versa.

30. Claims 17-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 11/899,611. Although the conflicting claims are not identical, they are not patentably distinct from each other because if one practiced the claimed invention of instant claims, one would necessarily achieve the claimed invention of copending application and vice versa.

31. Instant claims are drawn to a method for treating shock comprising administering to a subject in need of such treatment an effective amount of a peptide of Formula II. Claims 23-28 are drawn to a method of treating shock, wherein shock is due to myocardial infarction, vascular surgery...surgical procedures and stroke, and organ dysfunction of grafter organs, and so forth.

32. Claims 1-4 of copending application are drawn to a method of treating reperfusion injury in a subject comprising administering to the subject a peptide of SEQ ID NO:294, that is the same as the instant SEQ ID NO:3. The specification of the reference discloses that a healing effect occurs with a drug for the therapy and/or prevention of a reperfusion trauma following a surgically or pharmaceutically induced restoration of the blood flow such as, after cardiac infarction, apoplectic stroke, after vascular surgery...(see paragraph [0066] of instant specification US 2009/0137464 A1).

33. Therefore, if one of ordinary skill in the art practiced the claimed invention of the instant claims, one would necessarily achieve the claimed invention of copending application 11/899,611, and vice versa.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

34. Claims 17-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6-7 of copending Application No. 12/121,533. Although the conflicting claims are not identical, they are not patentably distinct from each other because if one practiced the claimed invention of instant claims, one would necessarily achieve the claimed invention of copending application and vice versa.

35. Instant claims are drawn to a method for treating shock comprising administering to a subject in need of such treatment an effective amount of a peptide of Formula II. Claims 23-28 are drawn to a method of treating shock, wherein shock is due to myocardial infarction, vascular surgery...surgical procedures and stroke, and organ dysfunction of grafter organs, and so forth.

36. Claims 6-7 of copending application are drawn to a pharmaceutical composition containing a compound of the general formula (I) and medical use of a compound of the general formula (I). The instant specification discloses that diseases belonging to the group are those in context with autoimmunity…a healing effect harmful to the tissue…important to the treatment of shock (see p. 11).

37. Therefore, if one of ordinary skill in the art practiced the claimed invention of the instant claims, one would necessarily achieve the claimed invention of copending application 12/121,533, and vice versa.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

38. Claims 17-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-7 of copending Application No. 12/121,544. Although the conflicting claims are not identical, they are not patentably distinct from each other because if one practiced the claimed invention of instant claims, one would necessarily achieve the claimed invention of copending application and vice versa.

39. Instant claims are drawn to a method for treating shock comprising administering to a subject in need of such treatment an effective amount of a peptide of Formula II. Claims 23-28 are drawn to a method of treating shock, wherein shock is due to myocardial infarction, vascular surgery...surgical procedures and stroke, and organ dysfunction of grafter organs, and so forth.

40. Claims 6-7 of copending application are drawn to a pharmaceutical composition comprising peptide of formula I, medical use of a compound of the general formula (I). The medical use is not defined in the claims. The instant specification discloses that diseases belonging to this group are those in context with autoimmunity… a healing effect harmful to the tissue…important to the treatment of shock (see p. 11).

41. Therefore, if one of ordinary skill in the art practiced the claimed invention of the instant claims, one would necessarily achieve the claimed invention of copending application 12/121,544, and vice versa.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

42. Claims 17-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 4-5 of copending Application No. 12/158,670. Although the conflicting claims are not identical, they are not patentably distinct from each other because if one practiced the claimed invention of instant claims, one would necessarily achieve the claimed invention of copending application and vice versa.

43. Instant claims are drawn to a method for treating shock comprising administering to a subject in need of such treatment an effective amount of a peptide of Formula II. Claims 23-28 are drawn to a method of treating shock, wherein shock is due to myocardial infarction, vascular surgery...surgical procedures and stroke, and organ dysfunction of grafter organs, and so forth.

44. Claims 1-2 and 4-5 of copending application are drawn to a method for treating hemorrhagic shock or the sequels thereof, comprising administering to an animal a peptide comprising the N-terminal sequence GHRPLDKKREEAPSLRPAPPPISGGGYR, that is the same as the instant SEQ ID NO:3.

45. Since the copending application is drawn to a method of treating hemorrhagic shock, if one of ordinary skill in the art practiced the claimed invention of the instant claims, one would necessarily achieve the claimed invention of copending application 12/158,670, and vice versa.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

46. Claims 17-28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 7,494,973. Although the conflicting claims are not identical, they are not patentably distinct from each other because if one practiced the claimed invention of instant claims, one would necessarily achieve the claimed invention of copending application, and vice versa.

47. Instant claims are drawn to a method for treating shock comprising administering to a subject in need of such treatment an effective amount of a peptide of Formula II.

48. Claims 1-3 of US Patent No. '973 are drawn to a method of treating rejection of a transplanted tissue in a subject comprising administering to the subject a peptide of SEQ ID NO: 294. The specification of the reference teaches that the invention consist in the preparation of pharmaceutical compositions for the therapy or prevention of local and/or generalized inflammation in the body in case of infectious genesis, based upon an auto-immune reaction, based upon a rheumatic disease, based upon a disorder in the immune system, based upon genetic disease, for the prevention and/or therapy of the rejection occurring after organ transplants, and so on (see column).

49. The instant claims 23-28 claim that the shock is associated with one or more of the group comprising bacterial toxins, hemorrhagic shock following viral infection…infectious agents or autoimmune diseases, organ failure after organ injury…vascular surgery, clamping of organs…organ dysfunction of grafted organs, and so on.

50. Therefore, if one practiced the claimed invention of the instant claims, one would necessarily achieve the claimed invention of the U.S. Patent No. '973 and vice versa.

Response to Applicant's Arguments

51. Applicant argues that "upon indication of allowable subject matter, Applicants will consider the need to file one or more terminal disclaimers to obviate the concerns of these nonstatutory obviousness-type double patenting rejections."

52. Applicant's arguments have been fully considered but have not been found persuasive. Until properly executed terminal disclaimers are filed and approved by the Office, Double Patenting rejections are maintained.

New Objection

53. Claim 17 is objected to for the following minor informality: Claim 17 recites amino acid sequence DKKREEAPSLRPAPPPISGGGYR. The peptide sequence is missing the sequence identifiers. The proper way to claim a peptide sequence is for example, DKKREEAPSLRPAPPPISGGGYR (SEQ ID NO:1) (see 37 CFR 1.821(d)). This error should be corrected.

New Rejection

35 U.S.C. 102

54. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

55. Claims 17-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Petzelbauer, Peter (WO 02/48180 A2, filed with IDS, published on June 20, 2002). This publication is in German, and machine translation is used and provided.

56. WO 02/48180 A2 teaches peptides or proteins of general formula (I and II) where R_1 and R_2 are independently hydrogen, a saturated or unsaturated hydrocarbon group with 1 to 3 carbon atoms, Z_1 is histidine or proline, Z_2 is an arginine, a peptide group or protein group with arginine at the initial terminus (see abstract, claims 1-2), meeting the limitation of instant claims 17-22. The reference teaches the same sequence as instant sequence DKKREEAPSLRPAPPPISGGGYR (see SEQ ID NO: 11 and claim 5), meeting the limitation of claim 17. Furthermore, the reference teaches the sequence GHRPLDKKREEAPSLRPAPPPISGGGYR (see SEQ ID NO: 11), meeting the limitation of claims 17-22. The reference teaches the method of treating inflammation due to inflammation of the body, autoimmune reaction, genetic disease, trauma, organ transplant and so on (see claims 7-17). Furthermore, the instant claims 23-28 recite "...wherein the shock is associated with one or more groups comprising bacterial toxins, haemorrhagic shock following viral infection...infectious agents or autoimmune

diseases, organ failure…and so on (see claims 23-28). WO 02/48180 A2 reference teaches the method of preventing inflammation in a subject comprising administering to the subject an effective amount of a peptide having the general formula II, wherein the inflammation is due to a condition selected from the group consisting of an infection, an autoimmune condition, a rheumatic disorder, or a disorder of the immune system (see claims 7-17). Since the cause that leads to inflammation and shock is the same, the method of treating inflammation would necessarily treat shock, and vice versa. Thus, the reference anticipates instant claims 17-28.

Conclusion

57. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie Ha/
Examiner, Art Unit 1654